

REMARKS

Status of the Claims

Claims 1-25 are pending and claims 19-25 are under consideration in this application. Claims 1-18 are withdrawn as allegedly drawn to separate inventions. Claims 19-25 stand rejected.

Claims 1-18 have been cancelled without prejudice or disclaimer and Applicants reserve the right to pursue the subject matter of the cancelled claims in one or more divisional applications. Claims 19 – 25 have been amended. New claims 26-41 have been added. Support for the amendments and new claims added herein can be found in the original claims and throughout the specification as filed, e.g., paragraphs [0060], [0064]-[0066], [0088], [0089], and [0101] of the published application (US Publication No. 2006/0121033). No new matter has been added.

Following entry of the amendments and new claims added herein, claims 19-41 will be pending and under consideration in this application.

Applicants' amendments or cancellation of claims should in no way be construed as acquiescence to any of the Examiner's rejections. The amendments to the claims are being made solely to expedite prosecution of the present application and/or to clarify the subject matter claimed. Applicants reserve the right to further prosecute the same or similar claims in the instant or in one or more subsequent patent applications claiming priority to the instant application.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the outstanding Office Action.

Restriction Requirement

Applicants thank Examiner Li for the telephone call, and further telephone conversation, of September 4, 2008 with Applicants' representative Dr. Jennifer Holmes regarding a Restriction Requirement and a provisional election. Applicants hereby confirm the telephonic election of the invention of Group III, which is inclusive of original claims 19-25 and instant claims 19-41. This election was made *without* traverse.

Objection to the Title

At page 4 of the Office Action, the title was objected to as allegedly not indicative of the invention to which the claims are directed. Solely in the interest of expediting prosecution of this application, Applicants have herein amended the title to “METHODS OF IDENTIFYING AND ISOLATING CELLS EXPRESSING DC-SIGN.” The amendment obviates the objection.

Rejection Under 35 U.S.C. § 112, first paragraph (Enablement)

At pages 4-6 of the Office Action, claims 19-25 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. According to the Office Action, “the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.” (See Office Action at page 6.) Applicants respectfully traverse.

While not conceding to any aspect of the Examiner’s stated reasons for rejection, amended claim 19 and the claims dependent therefrom are drawn to methods for enriching the percentage of macrophages in a sample of cells, which methods include contacting a sample of cells with an agent that binds to DC-SIGN and separating cells that bind to said agent from cells that do not bind to said agent. The practice of such methods is described in detail in, and exemplified by, the specification. For example, at paragraphs [0064] and [0065] the specification describes suitable methods for separating cells bound by an agent that binds to DC-SIGN including, without limitation, the use of a column, matrix, or magnetic or paramagnetic beads. Furthermore, in the working examples, the specification exemplifies the contacting of a sample of cells (a blood sample from a person with rheumatoid arthritis) with an agent that binds to DC-SIGN (an antibody that binds to DC-SIGN) and subsequent separation of cells that bind to the agent using fluorescence-activated cell sorting (FACS). In this regard, nothing more is required under the law.

The Office Action also states that “neither the specification nor the prior art teaches **any** plant lectins, antibiotics, or **any** sugars bind to DC-SIGN.” (See Office Action at page 6; emphasis added.) Thus, Applicants understand the Examiner’s position to be that the original claims were not enabled unless the specification and/or the art disclose(s) that each and every plant lectin, antibiotic, and sugar bind to DC-SIGN. Applicants respectfully disagree.

First, according to the MPEP, it is **not** required for enablement of the claims that **any** sugars, **any** antibiotics, or **any** plant lectins be useful in the practice of the claimed methods. Rather, the standard “is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art.” See, e.g., MPEP § 2164.08(b) citing *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984).

Second, it is **not** required for enablement of the claims that the specification or the art exemplify the use of each possible species of a claimed genus. The MPEP states that

[f]or a claimed genus, **representative examples** together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art...would expect the claimed genus could be used in that manner without undue experimentation. (See MPEP § 2164.02; emphasis added.)

Applicants point out that the specification discloses a variety of genera and subgenera of suitable agents that bind to DC-SIGN including, without limitation, anti-DC-SIGN antibodies or antigen-binding fragments thereof, sugars, antibiotics, and proteins (see paragraphs [0052] and [0055]). Examples of each genus of agent were also known in the art at the priority date of the application and described in the specification. For example, the specification states that proteins such as gp120, isolated ICAM-receptors, and analogs or DC-SIGN-binding fragments of any of the foregoing can bind to DC-SIGN and are useful in the practice of the claimed methods (*Id.*). In another example, the specification provides two exemplary monoclonal antibodies, AZN-D1 and AZN-D2, that are useful in performing the claimed methods (see specification at, e.g., paragraphs [0060]-[0062]). In yet another example, the specification describes exemplary species of sugars suitable for use in the claimed methods including, e.g., N-acetyl-D-glucosamine, galactose, mannose carbohydrates (e.g., mannan and D-mannose), and fucose carbohydrates such as L-fucose (see specification at, e.g., paragraph [0052]). In fact, the Office Action even acknowledges that “sugar (the genus) encompasses a mannose carbohydrate and a fucose carbohydrate (species).” (See Office Action at page 6.)

Third, the common structural characteristics of ligands that bind to DC-SIGN were known in the art at the time of filing. For example, Geijtenbeek et al., *Journal of Leukocyte Biology*, vol 71 (2002) (“Geijtenbeek,” attached as Exhibit A) teaches that the “EPN or QPD sequences” within the

carbohydrate-recognition domain (CRD) of DC-SIGN “are essential in recognizing mannose- and galactose-containing structures, respectively” (page 922, left column). Geijtenbeek further teaches that “DC-SIGN recognizes high-mannose residues located more internally within a glycan structure” (page 922, left column). Therefore, one of skill in the art reading the specification would be able to determine whether a sugar or an antibiotic can bind to DC-SIGN based on its structure, in light of the general knowledge in the art and the particular details and representative examples that have been specifically disclosed in the specification.

Moreover, methods for determining whether an agent binds to DC-SIGN were well known in the art of molecular biology at the priority date of the application and are described in the specification. For example, the specification states that “peptidomimetic compounds and small drug molecules...can be identified using phage display techniques.” See, e.g., paragraph [0052] and paragraph [0051] of the published application (US Publication No. 2006/0121033), citing PCT Publication No. WO93/01820.

In view of the foregoing, Applicants respectfully submit that the specification amply enables the claimed methods and that the skilled artisan at the priority date of the application could practice the claimed methods with little more than routine experimentation. Accordingly, the Examiner is requested to reconsider and withdraw the rejections under 35 U.S.C. § 112, first paragraph.

Claim Objection

At page 6 of the Office Action, claim 22 was objected to because it recites “a mannose carbohydrate, a fucose carbohydrate and a sugar, whereas the sugar (the genus) encompasses a mannose carbohydrate and a fucose carbohydrate (species).” Applicants have presently amended claim 22 (in conjunction with new claim 31), which amendment renders the objection moot.

CONCLUSION

For at least the reasons set forth above, Applicants submit that all grounds for objection and rejection have been overcome and that all of the pending claims, including new claims 26-41, are now in condition for allowance, which action is earnestly requested. Applicants do not accede to any positions of the Examiner not specifically addressed above.

In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at the number provided below.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. ALXN-P01-095 from which the undersigned is authorized to draw.

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Respectfully submitted,

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